UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

Antimicrobials Division (AD)
September 4, 2013

EPA Reg#: 9402-RT		DP Barcode: 411425	
		Submission #: 933136	
Product name: Hitman Wipe		Registrant: Kimberly – Clark Global Sales, LLC	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry	
Agency due date: 09/23/13		PSB received date: 05/02/13	
CTT received date: 05/02/13		Science due date: 07/30/13	
Formulation type: EUP		Sub data package due date: 08/09/13	
Integrated system: []	Non integrated system:[X]	Food use: []	Non food use: [X]
Action Code: A540	Date Completed: 08/14/13		

PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
000595	7722-84-1	Hydrogen peroxide	0.94

069208	148788-55-0 and 148812-65-1	Didecyl dimethyl ammonium carbonate (and) Didecyl dimethyl ammonium bicarbonate	1.25

Test Lab: N/A.	
MRID(s): 49089900, 49089901, 49089902, 49089904	
Approver: Karen P. Hicks	Approved date:
Guideline: 830 Groups (A & B)	
Comments:	

for Juan:
10/06/13

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EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

September 4, 2013

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 9402-RT
Product name: Hitman Wipe
DP # 411425

From: Juan Negron, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

for Juan

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble / Drusilla Copeland
PM Team 31
Antimicrobials Division (7510P)

APPLICANT: Kimberly – Clark Global Sales, LLC
Action code: A540
Due date: 09/23/13

Product Formulation
Active Ingredient(s)

	% by wt.
Hydrogen peroxide	0.94
Didecyl dimethyl ammonium carbonate (and) Didecyl dimethyl ammonium bicarbonate	1.25

BACKGROUND:

On behalf of the registrant, Kimberly – Clark Global Sales, LLC, the consultant, Scientific & Regulatory consultants, Inc., has submitted an application for a new registration of Hitman Wipe. The product is a non-integrated, non-food and end-use product. The product is categorized as a bactericidal, Virucidal, mildewstat, non-food contact sanitizer, residual self sanitizer, deodorizer, and a cleaner. The product is a saturated towelette/wipe for hard non-porous surfaces in residential and non-healthcare institutional and industrial setting. The Product Chemistry reviewer has reviewed the following documents:

- A letter, dated 04/01/13.
- A transmittal document, dated 04/01/13, MRID # 49089900.
- Application for pesticide registration, dated 04/01/13.
- Data matrix, dated 04/01/13.
- A draft label, dated 03/22/13.
- Confidential Statements of Formula (CSFs), dated 04/01/13, for the basic and alternate # (1 & 2) formulations.
- A study titled "PRODUCT CHEMISTRY Discussion and Data Waivers" OPPTS 830.1550 – 1800; Volume 2 MRID # 49089901.
- A study titled "PRODUCT CHEMISTRY Identity, Composition and Analysis" OCSPP 830.1550-1750; Volume 3 MRID # 49089902.
- A study titled "Hitman Wipe: Enforcement Analytical Method" MRID # 49089903.
- A study titled "Physical and Chemical Characteristics of Hitman Wipe: Color, Physical State, Odor, Oxidation/Reduction, Flammability, pH, Viscosity and Relative Density" MRID # 49089904.

FINDINGS:

1. The CSFs, dated 04/01/13, for the basic and alternate #s (1 & 2) formulations are revised.

2. The CSFs and the label have the same nominal.

3. The certified limits for the active ingredients (AIs) do not meet the EPA standard certified limits. The registrant submitted a letter requesting wider certified limits for the AIs.

4. The OPPTS Guidelines Group A product chemistry data requirements applicable to end-use products have been met. See table below.

5. The OPPTS Guidelines Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics). See table below.

CONCLUSIONS:

The CSFs, dated 04/01/13, for the basic and alternate #s (1 & 2) formulations are acceptable. The 830 Guidelines groups "A & B" product chemistry requirements for non-integrated end-use products were found to be acceptable, with the exception of the OPPTS Guidelines: 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics".

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [x]No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food use:

Yes [x] No [ ]

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC (%)	LCL (%)	UCL (%)
Hydrogen peroxide	0.94	0.70	1.18
Didecyl dimethyl ammonium carbonate (and) Didecyl dimethyl ammonium bicarbonate	1.25	1.13	1.38

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49089902
830.1600 Description of Materials	A	49089902
830.1620 Production Process[2]	NR *[Not required for products produced by a non-integrated system.]*	49089901 & 49089902
830.1650 Formulation Process[3]	A	49089902
830.1670 Formation of Impurities[4]	NR *[Not required for products produced by a non-integrated system.]*	49089901 & 49089902
830.1700 Preliminary Analysis[5]	NR *[Not required for products produced by a non-integrated system.]*	49089901 & 49089902
830.1750 Certified Limits[6]	A	49089902
830.1800 Enforcement Analytical Method[7]	A	49089903
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Colorless at 23° C.	49089904
830.6303 Physical State	A	Liquid at 23° C.	49089904
830.6304 Odor	A	Slight odor at 23° C.	49089904
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	**Water and monoammonium phosphate** ~ no signs of reaction (upon mixing & after 24 hours exposure). **Powdered Iron**~ reaction slow to start; Gas given off & bubbled; Turned olive green in color; temperature rose 14.9 ° C. After 24 hours exposure – some iron turned orange/brown on the vial walls, possible rust. **Potassium permanganate** ~ Gas given off and bubbled; turned brown in color; temperature rose 10 ° C; After 24 hours exposure the sample thickened like a gel.	49089904
830.6315 Flammability/ Flame Extension	A	No flash, sample boiled at 98° C.	
830.6316 Explodability	A	The product contains no explosive ingredients.	49089901
830.6317 Storage Stability	G	A one-year storage stability study is currently underway.	49089901
830.6319 Miscibility[1]	A	The product is not an emulsifiable liquid to be diluted with petroleum solvents.	49089901
830.6320 Corrosion Characteristics	G	A one-year corrosion characteristics study is currently underway.	49089901
830.6321 Dielectric Breakdown Voltage	A	The product is not used in/on/around electrical equipment.	49089901
830.7000 pH[2]	A	3.69 (1%) at 25° C. 2.97 at 25° C, neat.	49089904

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7050 UV/Visible Absorption	NR	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The average viscosity was reported to be 4.7002 mm^2/s at 21° C ; 2.1296 mm^2/s at 43° C.	49089904
830.7200 Melting Point/Melting Range	NR	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NR	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	1.00811 at 23° C.	49089904
830.7370 Dissociation Constants in Water	NR	*[Not required for end-use products.]*	49089901
830.7550/830.7560/830.7570 Partition Coefficient	NR	*[Not required for end-use products.]*	49089901
830.7840/830.7860 Water Solubility	NR	*[Not required for end-use products.]*	49089901
830.7950 Vapor Pressure	NR	*[Not required for end-use products.]*	49089901

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water